FDA Regulation of Tobacco Products Is Simply Designed to Put the Tobacco Industry Out of Business

H.R. 2147 would give the Food and Drug Administration ("FDA") vast discretionary authority to regulate the manufacture, distribution, sale, labeling, advertising and promotion of tobacco products in a manner in which food and drugs are regulated. The bill also establishes minimum requirements in each of these categories which, in many instances, go far beyond those applicable to other FDA-regulated products.

This broad and expansive grant of authority to the FDA in combination with the regulatory and enforcement tools available to the agency and the public under food and drug law, and the bill's vague and ambiguous statutory standards would create a complex and unpredictable regulatory scheme that would allow anti-smoking zealots to conduct guerilla warfare against the tobacco industry, with the goal of eventually putting it out of business. This battle would take place at the expense of the FDA's already inadequate resources and thus would divert the FDA from its primary responsibilities of approving life-saving drugs and medical devices and ensuring the safety of our nation's food supply. And to what end? Those government officials and anti-smoking advocates who advocate FDA regulation of tobacco products have repeatedly proclaimed that, in their view, no tobacco product can ever be "safe" or even "safer."

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The Synar bill, among other things, would:

- require the public disclosure of *all* ingredients and constituents contained in a tobacco product, regardless of how small the quantity or how fully proven the safety;
- give the FDA authority to ban or limit any such additives on the basis of a vaguely worded and undefined standard;
- classify as "drugs" nicotine-containing products which are not traditional tobacco products, even though no claims of a therapeutic nature are made;
- prohibit the use of truthful descriptors of brand characteristics, such as low-tar/nicotine and "light", unless the FDA determines that such claims are in the interest of public health;
- authorize the FDA to modify the current set of warnings and require manufacturers to notify the public of any information related to tobacco products that the FDA deems necessary;

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- require the FDA to regulate tobacco product advertising as though it were prescription drug advertising;

- impose registration and user fee requirements on tobacco manufacturers, based on brand market share;

- create subpoena authority over *any* document related to tobacco product manufacturing and access, during an FDA inspection, to any document related to the tobacco product; and

- establish an advisory committee, with no tobacco or related industry representation, to make recommendations regarding the FDA's regulatory authority over tobacco products.

Despite its deceptive simplicity, proposed FDA regulation of tobacco products is inappropriate, unnecessary, overreaching and unwise. It is *inappropriate* because the system of FDA regulation is grounded in ensuring product safety. By contrast, proponents of FDA regulation of tobacco products are not trying to promote what they would consider "safe" or "safer" tobacco products. Rather, such proponents have as their main goal making tobacco products unavailable to the public.

It is *unnecessary* because tobacco products are already extensively regulated, from seedbed to distribution and use, at the federal, state and local levels. For example, Congress has already assigned the responsibility for the safety and disclosure of cigarette ingredients to HHS under an 1984 law. Each year since 1986, ingredient lists have been submitted to HHS pursuant to this law. And this same law authorizes HHS to study the health effects of ingredients and to so report to Congress, as it deems appropriate. To date, HHS has given no indication that its review has created any basis for concern. Indeed, former HHS Secretary Louis Sullivan stated in 1990 congressional testimony that additional ingredient regulation is "unnecessary."

The Synar bill is *overreaching* in that it would subject tobacco products to certain standards and requirements that other FDA-regulated products do not have to meet. These requirements have no purpose except to halt the marketing of tobacco products.

It is *unwise* because the FDA can ill-afford to divert its insufficient resources, let alone to become embroiled in the highly politicized and perennial debate over tobacco products.

So, why is FDA regulation of tobacco products being proposed? Because the existing FDA regulatory system as augmented by the Synar bill provides repeated opportunities for the harassment of a controversial product. The Synar bill makes a thinly veiled attempt to stave off the claim that H.R. 2147 is in fact intended to serve as *de facto* prohibition of tobacco products over time by stating that the FDA may not prohibit the sale or distribution of a tobacco product

solely on the basis that, in the words of H.R. 2147, "tobacco causes disease." However, the regulatory mechanisms available under the Food, Drug, and Cosmetic Act ("FDCA"), as enhanced by the Synar bill, would subject tobacco products to a morass of unpredictable regulations, based on vague statutory standards, some of which, from a practical standpoint, simply could not be met, or if they could be met, would be highly susceptible to manipulation by anti-smoking zealots. The result could be that tobacco products would become prohibitively expensive, unpalatable and/or inaccessible.

Thus, through the back door, which would be opened by FDA regulation of tobacco products, anti-smoking activists could accomplish what the Congress has declined to do affirmatively, which is to ban the sale of tobacco products. How this goal could be accomplished is illustrated below.

Ingredient Approval

The FDA likely would use its food additive approval mechanism as a model for approving tobacco ingredients. This ingredient approval system provides numerous mechanisms that could be used to harass a controversial product such as tobacco, allows a great deal of official discretion and is sensitive to public pressure.

- The present additive approval process is a lengthy and difficult undertaking which provides a number of tools for keeping a product off the market for a number of years.

- Establishing the safety of additives, in large part, is influenced by pressures created by outside interest groups. The regulatory scheme calls for the participation of *all* interested parties. Such a scheme works nicely for foods, or life-saving drugs, because the vast majority of foods and drugs do not raise great emotional or political issues. For a product like tobacco, however, it provides the perfect weapon for anti-tobacco forces to try to keep tobacco products off the market. Anti-smoking groups could press regulators on every finding made regarding the safety of cigarette additives. If additives critical to the present manufacturing process or user acceptance were not found to be "safe," as defined by the FDA, the current marketing of tobacco products could be halted outright. For example,

  -- FDA regulations allow any "adversely affected" person (a term construed very broadly by the FDA) to file objections to a proposed order allowing the use of a food additive and to request a hearing on such order.

  -- In addition, citizens may file petitions asking the FDA to act, or refrain from acting, on any issue within the agency's jurisdiction, including approval of additives.

- Also, the Synar bill would not necessarily even provide the protections afforded food additives. For example, food ingredients "generally recognized as safe" ("GRAS") are not subject to the FDA's lengthy food to additive approval process. The GRAS concept, however, is not part of the Synar bill. And, even if the FDA gratuitously grafted the GRAS concept onto its tobacco additive regulations -- an unlikely scenario -- opportunities for guerilla warfare by the anti-tobacco groups would still exist.

- In sum, the additive approval process could be used by the FDA and interest groups to obstruct the marketing of tobacco products or to require manufacturers, on an indefinite basis, to forgo the use of those ingredients responsible for the palatability of certain brands.

Labeling

1. ***Ingredient and Constituent Disclosure.*** The Synar bill would require that all additives in and constituents of a tobacco product be listed on package labeling.

- By contrast, food labeling laws, for example, require only a common sense listing of ingredients. Flavorings do not have to be described individually, and incidental additives, such as processing aids, do not have to be listed at all.

- Likewise, constituents arising during the cooking process do not have to be disclosed at all.

- The required disclosure of every tobacco flavoring would force tobacco manufacturers to give away their most commercially valuable asset -- the secret formula for each tobacco product brand. This would fly in the face of one of the most basic principles of American law: the protection of trade secrets.

- Testing of every minute constituent in tobacco smoke (about 4,000) would be needed in order to meet the requirement that all constituents in tobacco smoke be disclosed on tobacco product labeling. This task could take years and years to accomplish. This would provide the perfect tool by which to keep tobacco products off the market while such testing occurred.

- The onerous and detailed disclosure requirements would require manufacturers to incur tremendous costs in packaging redesign and production.

2. ***Low-Tar/Nicotine Claims.*** The bill's effective prohibition of truthful descriptors, like low-tar or low-nicotine, would not allow consumers to distinguish among these brands and, therefore, may discourage the marketing of such products altogether.

3. ***In General.*** The FDA's catchall authority to require the disclosure to the public of any information deemed necessary, by any means, would allow it to require information on packages far in excess of the natural limits of readable, product labeling, or lengthy explanative documents providing whatever information the FDA felt necessary.

New Products

The bill would allow the FDA to declare that nicotine-containing products not meeting the traditional definition of a tobacco product be classified as "drugs" under the FDCA.

- This would serve to effectively halt the development of innovative new tobacco products because drugs must have demonstrated *therapeutic benefits* before they can be sold.

- This would permit the FDA to establish, by regulation, a definition of a traditional tobacco product, regardless of the long-existing rules for measuring a product's intended use. In effect, *any* tobacco product declared not to meet the traditional definition could not be marketed in the U.S.

Advertising Regulation

The Synar bill requires, at a minimum, that regulations governing the advertising of tobacco products be consistent with those applicable to prescription drugs. This means that:

- Manufacturers would be required to submit advertising copy to the FDA for review, possibly prior to its use, and have it censored by the agency. This provides fertile ground for the anti-smoking advocates who would like to see all tobacco advertising banned.

- Prescription drug advertising requirements are aimed at physicians, not consumers. As such, they are inappropriate for a consumer product such as tobacco products, and, moreover, they would circumvent congressional intent in creating the simple and succinct warnings that now exist for consumers of tobacco products.

Investigative and Enforcement Mechanisms

- Regulation under the authority of the FDCA means that a whole array of investigative and enforcement tools may be used against tobacco manufacturers.

  -- Products may be seized without a prior judicial hearing and the manufacture of tobacco products may be permanently enjoined.

-- Violations of the tobacco product regulations may be prosecuted criminally, including charging corporate officers who are unaware of conduct that allegedly caused the violation.

-- Noncompliance with FDA regulations could invite nongovernmental action, most notably product liability suits.

- In addition, the Synar bill gives the FDA enforcement tools that do not exist for most products currently regulated by the FDA.

  -- Any document relevant to tobacco manufacturing may be subpoenaed.

  -- Tobacco product factories may be inspected, during which *all* records, including personnel files and sensitive financial data, would be subject to FDA inspection and copying.